#### **REMARKS**

In response to the Office Action dated September 7, 2005, claims 9, 12, 21, and 24-47 have been canceled without prejudice or disclaimer. All remaining claims 1-8, 10-11, 13-20, and 22-23 have been amended. Many of the amendments are offered to make the claim language consistent, and are more in the nature of clarifying the language from the foreign application to be more consistent with the English language. As such, many amendments are not made directly in response to the rejections in the Office Action. No new claims have been added. No new matter has been added. Reexamination and reconsideration of the claims as requested is respectfully requested.

The Applicant notes that the drawings were objected to because none of the elements in Fig. 1 are labeled with indicia indicative of their function and the designations of the axes of Fig. 2 are not in English. Applicant attaches hereto one replacement sheet of drawings that amends the drawings as instructed in the Office Action. The Applicant respectfully requests the withdrawal of these objections.

On page 2 of the Office Action, claims 31 and 32 were rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The Applicant canceled claims 31 and 32 without prejudice or disclaimer, and not as an acquisition as to the appropriateness of these rejections in the Office Action. The Applicant's cancellation of these claims is for the purpose of moving further along in prosecution and focusing the prosecution on the remaining claims directed to a method for the treatment of skin areas affected by psoriasis, and receiving a notice of allowance. The Applicant respectfully asserts that the rejections are moot.

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On page 3 of the Office Action, claims 8-10 and 34-47 were rejected under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which is regarded as the invention. The Applicant canceled claims 9, and 34-47 without prejudice or disclaimer, and not as an acquisition as to the appropriateness of these rejections in the Office Action. The Applicant's cancellation of these claims is for the purpose of moving further along in prosecution and focusing the prosecution on the remaining claims directed to a method for the treatment of skin areas affected by psoriasis, and receiving a notice of allowance. The Applicant respectfully traverses this rejection, but has amended the application to overcome the rejections of remaining claims 8 and 10. Claims 8 and 10 have been amended. It is believed that all claims comply with 35 U.S.C. § 112.

On page 3 of the Office Action, claims 25, 26, 28, 34-38, 40, 46, and 47 were rejected under 35 U.S.C. §102 (b) as being anticipated by Chernoff (U.S. 6,135,994). The Applicant canceled claims 25, 26, 28, 34-38, 40, 46, and 47 without prejudice or disclaimer, and not as an acquisition as to the appropriateness of these rejections in the Office Action. The Applicant's cancellation of these claims is for the purpose of moving further along in prosecution and focusing the prosecution on the remaining claims directed to a method for the treatment of skin areas affected by psoriasis, and receiving a notice of allowance. The Applicant respectfully asserts that the rejections are moot.

On page 4 of the Office Action, claims 1-7, 11-19, 23, 24, 29, 30, 35-38, 40-42, and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Chernoff in combination with Sator, et al. The Applicant canceled claims 12, 24, 29, 30, 35-38, 40-42 and 47 without prejudice or disclaimer, and not as an acquisition as to the

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appropriateness of these rejections in the Office Action. The Applicant's cancellation of these claims is for the purpose of moving further along in prosecution and focusing the prosecution on the remaining claims directed to a method for the treatment of skin areas affected by psoriasis, and receiving a notice of allowance. The Applicant respectfully traverses this rejection, but has amended the application to overcome the rejections to remaining claims 1-7, 11, 13-19, and 23. In addition, claims 8-10, 20-22, 27, 31-33, 39, and 43-45 are rejected as being unpatentable over Chernoff in combination with Sator, et al. as applied to claims 1-7, 11-19, 23, 24, 29, 30, 35-38, 40-42, and 47, and further in combination with Mueller, et al. (U.S. 6,238,386). The Applicant canceled claims 9, 21, 27, 31-33, 39, and 43-45 without prejudice or disclaimer, and not as an acquisition as to the appropriateness of these rejections in the Office Action. The Applicant respectfully traverses this rejection, but has amended the application to overcome the rejections to remaining claims 8, 10, 20, and 22. Lastly, claims 15, 34, and 46 are rejected as being unpatentable over Chernoff in combination with Sator, et al. as applied to claims 1-7, 11-19, 23, 24, 29, 30, 35-38, 40-42, and 47, and further in combination with Bonis, et al. The Applicant canceled claims 34 and 36 without prejudice or disclaimer, and not as an acquisition as to the appropriateness of these rejections in the Office Action. The Applicant's cancellation of these claims is for the purpose of moving further along in prosecution and focusing the prosecution on the remaining claims directed to a method for the treatment of skin areas affected by psoriasis, and receiving a notice of allowance. The Applicant respectfully traverses this rejection, but has amended the application to overcome the rejection to remaining claim 15.

### 35 USC § 102 Rejections Based on Chernoff Are Moot

Apparatus claims 25, 26, and 28 were rejected under 35 U.S.C. §102 (b) as being anticipated by Chernoff (U.S. 6,135,994). The Applicant canceled these apparatus claims without prejudice or disclaimer, and not as an acquisition as to the appropriateness of these rejections in the Office Action. The Applicant's cancellation of these claims is for the purpose of moving further along in prosecution and focusing the prosecution on the remaining claims directed to a method for the treatment of skin areas affected by psoriasis, and receiving a notice of allowance. The Applicant respectfully asserts that the rejections are moot.

#### The Obvious Rejections Are Not Valid With respect to the Amended Claims

To establish *prima facie* obviousness of a claimed invention, the Examiner has the burden of proving that three basic criteria are met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure. All three of these criteria must be met in order to support a finding of *prima facie* obviousness of a claimed invention (*see, e.g.,* MPEP § 2142).

The Applicant submits that the Office Action as applied to the amended claims does not provide: 1) a teaching or suggestion or motivation to make the claimed combination with 2) the reasonable expectation of success being found in the prior art, and 3) not based on Applicants' disclosure. The Office Action cannot meet its burden with respect to the amended claims, and the rejections must be withdrawn. The following discussion of each reference of record described why the references do not present a *prima facie* case of obviousness.

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Applicant Traverses Any 35 U.S.C. § 103(a) Rejection Based on Chernoff

To the extent that the Office Action impliedly suggests a 35 U.S.C. § 103(a) rejection based solely on Chernoff for the method of treatment claims for skin areas affected by psoriasis, the Applicant respectfully traverses that rejection. The Applicant's amendment of the remaining claims removes Chernoff as a reference for obviousness based on several reasons discussed below.

The Applicant's remaining claims were amended to apply to <u>a treatment of skin</u> areas affected by psoriasis. For example, independent claim 1, as amended, now reads as follows:

Method for the treatment of skin areas affected by psoriasis comprising the steps of: determining the thickness of the epidermis in such skin areas; regulating the UV radiation dose generated by a laser depending on the epidermis thickness so detected; and directing the UV radiation dose onto the affected skin areas.

Chernoff describes a surgical method using an ultrasound transmitter to determine the depth of the tissue to be treated <u>beneath</u> the skin. See e.g., Chernoff, Col. 1, lines 57-59. In sharp contrast, the claimed invention determines the <u>thickness of the epidermis</u> in skin areas affected by psoriasis, and directs the UV radiation <u>onto the affected skin areas</u>. There is no mention in Chernoff as to the treatment of psoriasis.

The claimed invention uses the insight that the effect of UV radiation on the affected skin areas where psoriasis has developed into so-called plaques is primarily governed by the thickness of the epidermis within such plaques. There is an interrelationship between the thickness of the epidermis within these plaques and radiation dose that is just sufficient to effectively treat psoriasis. The regulation of the

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radiation dose in dependence on the epidermal thickness makes the whole treatment much more efficient and at the same time avoids negative side effects.

In contrast to the claimed invention, Chernoff treats a tissue in a certain depth beneath the skin. The laser power is adjusted only in view of the depth of the tissue beneath the skin, and not because of the thickness of the epidermis. The concepts of treatment for psoriasis and surgical techniques for reconstructive surgery are certainly different. Moreover, the Office Action offers no suggestion or motivation to derive the claimed invention's treatment of the disease psoriasis by modifying Chernoff, a reference that involves surgical procedures directed to cosmetic and reconstructive surgery, and has no mention of psoriasis.

Therefore, Chernoff alone does not render the claim invention to be obvious. As discussed below, neither Chernoff, alone, nor with any combination of the references of record present a *prima facie* case of obviousness.

Applicant Traverses 35 U.S.C. § 103(a) Rejection Based on Chernoff in combination with Sator, et al

First, the Office Action provides no suggestion or motivation to combine Chernoff, a reference that involves surgical procedures directed to cosmetic and reconstructive surgery, with Sator, et al, a study using high frequency ultrasound in PUVA-treated psoriasis patients. Thus, no *prima facie* case of obviousness has been presented in the Office Action.

Second, the claimed invention is not obvious in view of Chernoff in combination with Sator et al. Sator et al tests the skin thickness of PUVA patients <u>after</u> treatment. In other words, Sator et al only investigated the effect of PUVA treatment; Sator et al does not describe a new method for the treatment of psoriasis. Sator et al does not suggest

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adjusting laser power in view of the thickness of the epidermis, but only measures skin thickness when the treatment has already been preformed. Another difference between the invention and Sator et al is the use of PUVA therapy. According to PUVA therapy, UVA light is used in combination with a photosensitizing substance, e.g., psoralen. In contrast, the invention uses laser therapy. Moreover, and for example, the differences between PUVA therapy and the laser therapy of the invention are already described in the introductory portion of the application at page 1. Ergo, the obviousness rejections should be withdrawn.

# Applicant Traverses 35 U.S.C. § 103(a) Rejection Based on Chernoff in combination with Sator, et al. and Mueller

The Office Action provides no suggestion or motivation to combine Chernoff, a reference that involves surgical procedures directed to cosmetic and reconstructive surgery, with Sator, et al, a study using high frequency ultrasound in PUVA-treated psoriasis patients, and with Muller et al, a method involving endoscopic or invasive therapy using ultrasound and laser. As discussed in the preceding sections, the Office must provide support for this combination, and it has not done so. The Applicant incorporates by reference hereto, the prior discussions on obviousness of Chernoff and Sator et al as though repeated herein.

The references are different, and not properly combinable to achieve the claimed invention. Muller et al does not mention treatment of psoriasis (or any other skin disease), and invention pertains to treatment of psoriasis. Muller et al, unlike the claimed invention, describes and claims an instrument for performing invasive and endoscopic work. See generally, Muller et al specification and claims. The instrument in Muller et al involves cutting tissue in the interior of the body, and <u>not</u> applying a regulated radiation dose onto

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the skin areas. The purposes of the invention, on one hand, non-invasive treatment of affected skin areas by directing UV radiation, and Muller et al., on the other hand an invasive use of a laser internally are completely different. Thus, this reference teaches away from the invention since it involves an invasive endoscopic instrument, and the treatment of psoriasis according to the invention is non-invasive!

Thus, for all of the above reasons, no *prima facie* case of obviousness has been presented in the Office Action. Ergo, the obviousness rejections should be withdrawn.

Applicant Traverses 35 U.S.C. § 103(a) Rejection Based on Chernoff in combination with Sator, et al. and Bonis, et al

The Office Action provides no suggestion or motivation to combine the three references: Chernoff with Sator, et al, with Bonis et al. As discussed in the preceding sections, the Office must provide support for this combination, and it has not done so. The Applicant incorporates by reference hereto, the prior discussions on obviousness and impropriety of using Chernoff and Sator et al as though repeated herein. Bonis et al, background prior art, merely described the use of an 308 nm UVB excimer laser for treatment of psoriasis. However, there is no hint or suggestion to adjust the laser power in relationship to (or dependence upon) the thickness of the epidermis detected, and as claimed in the invention. Indeed, its appears the obviousness rejection combining the three references relies on applicant's disclosure, which is not permissible, to make the combination.

For all of the above reasons, this rejection should be withdrawn.

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## **CONCLUSION**

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. The amendments clarify the patentable invention without adding new subject matter. Applicant respectfully requests favorable reconsideration and early allowance of all pending claims.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicant's attorney of record, Michael B. Lasky at 952 253-4106.

Respectfully submitted,

Altera Law Group, LLC Customer No. /22865/

Date: December 7, 2005

By:

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